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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PAK, JOHN D	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,811	HENSLEY ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14,16-19,22,41 and 43-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14,16-19,22,41 and 43-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/15/2007 has been entered.

Applicant is advised of a typographical error on specification page 4, line 8: the U.S. Patent No. "5,688,32" is an obviously incorrect number. Correction is suggested.

Applicant is advised that should claim 17 be found allowable, claim 18 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 14, 16-19, 22, 41, 43-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) The high end of the carrier weight range is about 99.999 wt%. This is internally inconsistent with the minimum 0.185 wt% zinc salt and some undefined amount of the diffusion increasing agent that must also be present in the composition. The discrepancy is too large to fit under the "about" operator, particularly in view of the precision with which the high end of the carrier weight range is expressed (carried out to three decimal places).

(2) Independent claim 11 has been amended so that all claims now recite or read on the composition having following feature: about 75-99.999 wt% carrier comprising about 75-99.999 wt% water and a thickening agent. This feature can have various meanings and is therefore confusing and indefinite. The following interpretations are possible and one skilled in the art would not be able to determine which interpretation applies to the invention:

(a) carrier itself makes up about 75-99.999 wt%, and within that amount, 75-99.999 wt% of the carrier (i.e. about 56.25-99.998 wt% based on the total composition) is water only;

(b) same as above, except the 56.25-99.998 wt% based on the total composition is water + thickening agent;

(c) carrier is comprised of a thickener + about 75-99.999 wt% water; and

(d) carrier is made up of water + thickening agent, and the carrier comprises about 75-99.999 wt% of the composition.

(3) Claims 44 and 45, which depend on claim 11, use the term "thickener," but claim 11 recites "thickening agent." Use of consistent terminology is suggested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 14, 16-19, 22, 41, 43-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claim 11 has been amended so that all claims now recite or read on the composition having following feature: about 75-99.999 wt% carrier comprising about 75-99.999 wt% water and a thickening agent. As noted earlier in this Office action, this feature can have several different interpretations. The new matter ground of rejection (i.e. lack of descriptive support) is raised by interpretations (a), (b) and (c), supra.

Interpretations (a) and (b) as set forth above are clearly not conveyed since such low wt% as 56.25 wt% water + thickener was not originally disclosed. There is no specification basis for this meaning.

Interpretation (c) as set forth above is close but it too is not adequately supported by the original disclosure. Applicant argues this meaning in the remarks of 6/15/2007:

> % water and a thickening agent," as now set forth in the pending claims. The only exemplary gel compositions set forth in Hersh that include a thickening agent do not include about "75 wt % to about 99.999 wt % carrier comprising about 75 to about 99.999 wt % water." Applicants thus submit that claims 11, 14, 19, 22, 41, and 43-48 are novel in view of Hersh.

New Matter Issue: Does the originally filed disclosure provide adequate descriptive support for carrier that comprises a thickening agent + about 75-99.999 wt% water, wherein the total carrier amount is about 75-99.999 wt% based on the weight of the total composition, **without any other claim limitations as to composition physical form or physical characteristics**?

It must be kept in mind that the originally disclosed composition was directed to a **viscous** composition that came with certain viscosity requirements, and the composition was characterized as a **gel**. See original claims and specification (e.g. page 2, line 21). In fact, the original disclosure states that sprays (i.e. not necessarily viscous) were avoided during the development of the invention (specification page 4, line 7).

In contrast, the instant claims require nothing as to viscosity and read on containing up to about 99.999 wt% water (slightly less in claims 43, 45 and 47-48). Hence, such claim scope is in contradiction to the invention that was originally disclosed, because having that much water with no other specific claim feature to require the composition to be viscous or a gel means that the composition is readable on sprays.

It is noted that for every instance of original disclosure of 75-99.999 wt% "at least one carrier," the original disclosure also accompanied that disclosure with a further limitation of "viscous delivery composition," viscosity measurements, and/or gel characterization. Therefore, the amended claims fail to find adequate descriptive support for the entire scope of the claims, which is readable on, **for example**:

> A composition containing about 0.185 wt% to about 2.8 wt% ionizable zinc salt + diffusion increasing agent + "about 75 to about 99.999 wt % water and a thickening agent," wherein the composition is not limited as to "viscous delivery composition," viscosity measurements, and/or gel form.

Effective filing date of the claims, as presently amended

Before applying any prior art, determination of effective filing date is needed. Here, applicant has amended the claims to introduce new matter, which fails to find adequate descriptive support from the originally filed disclosure of this application or the parent application. Thus, the presently amended claims are not supported by the disclosure of the parent application; and consequently the effective filing date of this application cannot be 9/1/1998, the filing date of the parent application. For lack of a better date regarding new matter, the effective filing date for the purpose of this Office action will be taken as the filing date of this application, 11/25/2003.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 14, 19, 22, 41, 43-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Fust (US 6,344,210) for the reasons fully set forth in the Office action of 12/15/2006, which reasons are incorporated herein by reference.

Applicant's arguments are based on the position that the effective filing date of Fust does not quality the reference as prior art. However, the filing date of the application that issued as Fust's patent is 2/16/2001, and this date is earlier than the effective filing date of applicants' claims (see previous page of this Office action). Applicant's arguments are therefore found unpersuasive.

Claims 11, 14, 19 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Hersh (US 5,906,811).

Hersh explicitly discloses the following compositions (columns 20-21):

EXAMPLE 5

The following composition was prepared for administering the active ingredients as a gel (expressed as % by weight):

glycerin	42.0
poloxamer	18.0
ascorbic acid	2.0

- - - continued on next page - - -

sodium lauryl sulfate	1.2
natural peppermint oil	1.0
alpha tocopherol	0.75
green tea	0.5
calcium lactate	0.25
selenomethionine	0.20
sodium fluoride	0.20
L-glutathione	0.10
coloring agent	0.10
deionized water	balance
xylitol sweetener	15.00
zinc acetate	0.15

"A composition for delivering an active substance to a nasal membrane":

Note that the rejected claims are directed to compositions or a "system." Hence, given that Hersh's water + glycerin + oil containing gel composition could be delivered to a nasal membrane, this feature is met.

"about 0.185 wt % to about 2.8 wt % ionizable zinc salt": Hersh's 0.15 wt% zinc acetate meets this feature.

Applicant argues that 0.15 wt% is "outside the 0.185 wt % to about 2.8 wt % range." Applicant fails to appreciate the "about" modifier for 0.185 wt%, which is what the claims recite or read on.

The Examiner maintains that 0.15 wt% is within the claimed "about 0.185 wt %" (emphasis added), particularly since the claimed percentage numbers are so inaccurately and confusingly used. For example, even though minimum zinc salt amount is "about" 0.185 wt%, the maximum carrier amount is about 99.999 wt%. There

is a discrepancy of 0.184 wt% (0.001 – 0.185) for the zinc salt amount, if the maximum carrier amount were satisfied first. Since the remaining amount left over for the zinc salt, 0.001 wt%, is not very close to 0.185 wt%, applicant's claim-recited percentage numbers and "about" can at least be interpreted as encompassing Hersh's 0.15 wt%.

Additionally, applicants' claim 47 further supports the Examiner's position that Hersh's 0.15 wt% is within the claim language of independent claim 11. Claim 47, which depends on claim 11, reads on about 4 mM zinc ion. Hersh's 0.15 wt% zinc acetate is higher than that, at about 8 mM zinc ion concentration.

For these reasons, applicant's arguments are found unpersuasive.

"about" 4 to 60 mM zinc ion: Hersh's 0.15 wt% zinc acetate approximates to about 8 mM zinc ion concentration, as already discussed above.

Agent to increase diffusion of active substance through mucous in the nasal passage:

Hersh's glycerin can provide this function. So can Hersh's ascorbic acid. See applicant's specification page 16, lines 14-15.

Fluid: Hersh's glycerin, peppermint oil and water meet this feature.

Thickening agent: xylitol is a carbohydrate. Applicant recites carbohydrate as a thickening agent. This feature is met.

75-99.999 wt% carrier: the amount of glycerin + water + xylitol in Hersh's composition meets this feature. See above table.

Applicant argues that Hersh's composition does not contain a carrier comprising 75-99.999 wt% water. However, as already discussed earlier in this Office action, this is not the only claim interpretation possible: the claims are open to other claim interpretations. Hersh's disclosure meets at least one of the other possible claim interpretations.

The claims could be interpreted as reading on a carrier that makes up 75-99.999 wt% of the total composition, wherein the carrier comprises water + thickening agent. See relevant parts of claim 11, below.

> about 75 wt % to about 99.999 wt % ~~a~~ carrier comprising about 75 to about 99.999 wt % water ~~a fluid~~ and a thickening agent selected from the group consisting of ~~carrageegan~~ carrageenan, sugar, guar gum, ~~and~~ hydroxycellulose, methylcellulose, hydroxyethylcellulose, and other carbohydrates.

Since the second 75-99.999 wt% feature may not be referring to 75-99.999% of the first 75-99.999 wt% (because there is no descriptive support for 56.25%), a reasonable interpretation could be that the second percentage feature is merely duplicative of the first percentage feature. And since "comprising" is used, open claim language must be presumed. Based on this interpretation, Hersh's disclosure clearly shows a carrier that comprises water and carbohydrate, and the carrier comprises a percentage that is well within about 75-99.999 wt% of the composition.

Permeation enhancer: Hersh explicitly discloses glycerin. Applicant acknowledges that glycerin has permeation enhancing properties (specification page 9, lines 10-13). This feature is thereby met.

For these reasons, the claims are anticipated. All of applicant's arguments of 6/15/2007 have been addressed above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 14, 16-19, 41, 43-45 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hersh.

Hersh's teachings have been fully discussed above and the discussion there is incorporated herein by reference. Additionally with respect to this ground of rejection under section 103(a), it is noted that Hersh further teaches the use of zinc broadly (i.e. not just zinc acetate) and antimicrobial activity at concentration ranges of 0.1-3 wt%. See column 8, line 18; column 14, lines 46-49 & 65-66. Zinc gluconate is used in several of Hersh's examples (Examples 1-2) and disclosed as interchangeable (column 18, lines 66-67). With respect to a gel formulation, incorporation of bicarbonates and

"thickening agents" are disclosed, such as 0.5-5 wt% carrageenans, hydroxyethyl-cellulose or methylcellulose (column 12, lines 27-35).

The following is a discussion of each of the claim features.

"A composition for delivering an active substance to a nasal membrane": Note that the rejected claims are directed to compositions or a "system." Hence, given that Hersh's gel composition could be delivered to a nasal membrane, this feature is met.

"about" 0.185 to 2.8 wt% zinc salt: Hersh's 0.15 wt% zinc acetate example meets this feature.

about 0.185 to 2.8 wt% zinc gluconate: Hersh discloses the interchangeability of zinc gluconate and zinc acetate. This feature is thereby fairly suggested.

"about" 0.9 to 2 wt% ionizable zinc salt: Hersh utilizes zinc salts for antimicrobial purposes (column 14, lines 64-65) and discloses concentrations of 0.1-3 wt% as being suitable for activity (column 14, line 66). Applicant's concentration range is therefore fairly suggested.

"about" 4 to 60 mM zinc ion: Hersh's 0.15 wt% zinc acetate approximates to about 8 mM zinc ion concentration.

"about" 20-44 mM zinc ion: since Hersh discloses 0.1-3 wt% zinc salt, wherein the exemplified 0.15 wt% zinc acetate approximates to about 8 mM zinc ion, the instant claim feature is fairly suggested by Hersh's disclosure.

Agent to increase diffusion of active substance through mucous in the nasal passage:

Hersh's glycerin can provide this function. So can Hersh's ascorbic acid. See applicant's specification page 16, lines 14-15.

Thickening agent, 0.000001 to 5 wt%: xylitol is a carbohydrate. Applicant recites carbohydrate as a thickening agent. Feature of claim 11 is fairly suggested by xylitol.

Alternatively, xylitol can be categorized as a flavorant and Hersh's thickening agent is 0.5-5 wt% carrageenans, methylcellulose or hydroxyethylcellulose (column 12, lines 32-34).

Fluid: Hersh's glycerin, peppermint oil and water meet this feature.

75-99.999 wt% carrier: Applicant argues that Hersh's composition does not contain a carrier comprising 75-99.999 wt% water. However, as already discussed earlier in this Office action, this is not the only claim interpretation possible. Hersh's disclosure meets at least one of the other possible claim interpretations. The claims could be interpreted as reading on a carrier that makes up 75-99.999 wt% of the total composition, wherein the carrier comprises water + thickening agent. Since the second 75-99.999 wt% feature in claim 11 may not be referring to 75-99.999% of the first 75-99.999 wt% (because there is no descriptive support for 56.25%), a reasonable interpretation could be that the second percentage feature is merely duplicative of the first percentage feature. And since "comprising" is used, open claim language must be

presumed. Based on this interpretation, Hersh's disclosure clearly shows and suggests a carrier that comprises water and carbohydrate, and the carrier comprises a percentage that is well within about 75-99.999 wt% of the composition.

Permeation enhancer: Hersh explicitly discloses glycerin. Applicant acknowledges that glycerin has permeation enhancing properties (specification page 9, lines 10-13). This feature is thereby met.

A system for applying the composition to a nasal membrane: Nothing more than an applicator and the composition is required in applicant's system, so a mere container and a means for applying Hersh's gel would meet this claim feature. One having ordinary skill in the art would have been motivated to provide the gel in a container and then use some means to apply the gel to the route of administration. The "system" is thereby fairly suggested.

In sum, one having ordinary skill in the art would have recognized from Hersh's illustrative gel formulation Example 5 that the components can be modified in accordance with Hersh's complete teachings. Suitability of different concentrations of antimicrobial zinc salts such as zinc gluconate or zinc acetate would have been suggested from the antimicrobial needs of the particular end use. Hersh suggests the use of 0.5-5 wt% thickening agents such as carrageenans and cellulose derivatives such as hydroxyethylcellulose when the formulation is a gel, so incorporation of such

agents would also have been fairly suggested from the need to thicken the gel as appropriate.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

Applicant's remaining arguments have not been found persuasive. Applicant argues that xylitol is not taught as a thickening agent. The Examiner maintains that xylitol is expressly taught, and its functionality is present upon incorporation into Hersh's composition. In the context of a composition invention, the prior art need not teach the same intended use, so long as the same ingredient is taught or suggested. Otherwise, any composition patent claim, including applicant's, could be written around by later applicants claiming the same ingredients for different or previously unrecited functionalities.

Claims 11, 16-19, 22, 41-45, 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eby, III (Re. 33,465, hereinafter referred to as "Eby") in view of ES 2095183, HCAPLUS abstract 1994:638216, further in view of DE 3431727 (full English translation already of record).

Eby teaches reduction in the duration of common cold symptoms such as nasal drainage, nasal obstruction, sore throat, fever, cough, which are the result of upper respiratory infection (column 2, lines 57-64) by applying to the nasal mucosal membrane a zinc compound (column 2, lines 64-68). Nasal sprays, nasal drops, nasal ointments, nasal washes and nasal injections are taught (column 3, lines 3-7). Zinc gluconate is taught (column 3, line 24).

ES 2095183 discloses a drug delivery system composed of aqueous preparations that have a liquid form at room temperature but become gels at body temperature and adhere to the nasal mucosa (see the English abstract, HCAPLUS abstract 1997:283905). Less than 1% bioadhesive polymer such as hydroxypropyl cellulose and sodium chloride for isotonicity is disclosed (id.). Advantage of the gel intranasal delivery is controlled delivery (id.).

HCAPLUS abstract 1994:638216 discloses that bioavailability of nasally applied drugs is reduced by nasal mucociliary clearance, so nasal solutions contain polymers as thickeners to prolong the time between drug and the mucosa. Methyl hydroxypropyl cellulose and gellan gum (polysaccharide, i.e. a carbohydrate) are known thickeners in solutions of drugs that are applied nasally. The gellan gum is advantageous in that its viscosity increases when physiological level of cations are present.

DE 3431727 discloses that nasally applied zinc gluconate for treating viral ailments such as the common cold is at a concentration of 0.1 to preferably 2% (page 3 of translation, claims 1-2; page 6 of translation, last paragraph).

Eby does not expressly disclose every claim limitation or feature recited in the instant claims. Discussion of each feature and suggestion from the cited prior art is set forth below.

"A composition for delivering an active substance to a nasal membrane":

Eby provides the motivation to deliver Zn gluconate nasally. Nasal sprays, nasal drops, nasal ointments, nasal washes and nasal injections are taught (column 3, lines 3-7).

"about" 0.185 to 2.8 wt% zinc gluconate, "about" 0.9 to 2 wt% ionizable zinc salt, "about" 4 to 60 mM zinc ion, "about" 20-44 mM zinc ion:

Although Eby does not expressly disclose these concentrations, Eby teaches the nasal administration of zinc to treat the symptoms of the common cold. DE 3431727 provides the motivation to nasally administer zinc gluconate for treating viral ailments such as the common cold at a concentration of 0.1 to 2% (page 3, claims 1-2; page 6, last paragraph). 0.1% zinc gluconate calculates to about 2.2 mM and 2% zinc gluconate calculates to about 44 mM.

Motivation to select the drug delivery system of ES 2095183:

Eby discloses nasal sprays, drops, nasal ointments, but Eby does not provide a specific formulation disclosure for nasal administration. Hence, the ordinary skilled artisan

would have looked to nasal delivery technology that was available before applicant's effective filing date. ES 2095183 teaches that its aqueous drug delivery preparation is a liquid at room temperature but gels at body temperature and adheres to the nasal mucosa, thereby providing controlled delivery of active drugs. The ordinary skilled artisan would have been motivated to formulate zinc gluconate as taught by ES 2095183 with the expectation that zinc gluconate would be conveniently administered as a liquid that gels in the nasal mucosa to provide controlled delivery of the zinc to treat the common cold. The ordinary skilled artisan would have been further motivated from HCAPLUS abstract 1994:638216 that bioadhesives such as those utilized in ES 2095183 advantageously prolong the contact time between the mucosa and the delivered drug.

Agent to increase diffusion of the active substance through mucous in the nasal passage:

The drug delivery formulation of ES 2095813 contains sodium chloride to provide isotonicity.

Thickening agent, 0.000001 to 5 wt%: The drug delivery formulation of ES 2095813 contains bioadhesive polymers such as cellulose derivatives at an amount that is less than 1%. The example on page 3, column 4, lines 35-49 of ES 2095183 discloses 0.2 g of hydroxypropylmethylcellulose in 100 ml of water, i.e. 0.2 wt%.

Hydroxyethylcellulose as the thickening agent: From the general bioadhesive teaching to the specific hydroxypropylcellulose exemplified by ES 2095813,

hydroxyethylcellulose would have been an obvious modification since both cellulose derivatives are structurally similar cellulose ethers. Motivation to make the modification arises from the advantages of utilizing similar bioadhesive polymers to provide controlled delivery of the active substance.

75-99.999 wt% carrier: Different interpretations of this feature have already been set forth. The example on page 3, column 4, lines 35-49 of ES 2095183 discloses 12.15 g of ingredients in water to make up 100 ml. Such amount of water falls within applicant's water amount.

Permeation enhancer: The drug delivery formulation of ES 2095813 contains benzyl alcohol. An alcohol would provide solvent properties and would thus provide permeation enhancement.

A system for applying the composition to a nasal membrane:
Nothing more than an applicator and the composition is required in applicant's system, so a mere container and a means for applying Hersh's gel would meet this claim feature. One having ordinary skill in the art would have been motivated to provide the gel in a container and then use some means to apply the gel to the route of administration. The "system" is thereby fairly suggested.

In sum, the ordinary skilled artisan would have been motivated to select the nasal delivery formulation of ES 2095183 to nasally deliver Eby's zinc gluconate to treat symptoms of the common cold because said nasal delivery formulation would have

been expected to provide the advantages of controlled delivery and prolonged contact time in the mucosa. Inclusion and utilization of all other ingredients and features are fairly suggested as discussed above. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Applicant's arguments relative hereto have been given due consideration, but they were deemed unpersuasive.

Applicant's first argument about 75-99.999 wt% water has been discussed several times already. Other claim interpretations are possible. The Examiner maintains that the interpretation of up to about 99.999 wt% carrier comprising water and thickening agent has been fairly taught and suggested by the combined teachings of the prior art, as discussed above.

Applicant's second argument is that there is no suggestion to combine the references to form the claimed invention. Applicant argues that Eby does not suggest looking at other nasal application technologies, and even if that were not the case, combination with ES 2095185 would still not have been suggested because Eby disclosed other technologies, which were stated as being ineffective.

The Examiner must disagree. Eby discloses that prior art formulations are ineffective because "natural circulation removes zinc ions from the locus of the treatment more rapidly than the low application rate of zinc ions by the dosage replaces them" (column 2, lines 20-26). Eby further discloses, "method of application that does not maintain a sufficiently high level of zinc ions in the locus of treatment would not prevent continued viral replications (column 2, lines 30-33). Clearly, Eby suggests utilizing a nasal application technology that maintains the delivery of zinc ions at a high enough level to have an effect, which level is not removed in excess by the natural process. Considering that nasal application is inherently susceptible to runoff problems, Eby's teachings directly points to use of nasal application technology like the one taught by ES 2095183, which would adhere to the nasal mucosa and provide controlled delivery of an active ingredient. One having ordinary skill in the art, at a time prior to applicant's effective filing date, would have recognized the advantage that such nasal application technology provides and would thus have found it obvious to use the same to deliver Eby's nasal active ingredient.

For these reasons, this ground of rejection must be maintained.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 17-19, 22, 41 and 44-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,673,835 in view of ES 2095183 and DE 3431727 for the reasons of record.

Applicant requests reconsideration in view of the arguments and amendments set forth herein, but applicant has not argued against U.S. Patent No. 6,673,835 in the response filed with the RCE (6/15/2007). Since that is the primary "reference" here, applicant's lack of arguments necessitates maintenance of this ground of rejection without substantial further elaboration. Applicant's claim amendments are open to various interpretations, as already discussed many times in this Office action; and it is maintained that a carrier comprising 75-99.999 wt% of the composition, comprising

water and thickening agent is fairly suggested for the reasons of record – see the Office action of 12/15/2006, page 20.

For these reasons, all claims must be rejected again.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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